REMARKS

This is in full and timely response to the final Office Action mailed June 3, 2003, submitted concurrently with a Request for Continued Examination (RCE) and a Petition for an extension of time to within the first extended month. Reexamination and reconsideration in light of the above amendments and the following remarks is respectfully requested.

By this amendment, claims 10-11 were amended to place them in proper dependent form further limiting the method of claim 8. Claim 12 was amended to recite that the plasmid vector construct is encapsulated in a liposome formulation. Claims 14-15 were placed in independent form, and 17 were amended to depend from claim 15, and to recite additional method steps of encapsulating the plasmid. Support for this amendment can be found variously throughout the specification. No new matter was added. Claims 13 and 16 were cancelled without prejudice or disclaimer to their underlying subject matter. Accordingly, claims 8-12, 14-15 and 17-19 are pending for the Examiner's reconsideration, with claims 8, 12 and 14-15 being independent. Reexamination and reconsideration in light of the above amendments and the following remarks is respectfully requested.

Applicants' Representative thanks Examiner Hill and SPE Housel for the courtesies extended during the October 3, 2003 Telephone Interview.

Interview Summary

During the Interview, Applicants' Representative explained that the amendments to claims 10 and 11 should overcome all §101 and §112 issue, and the Examiner is invited to comment specifically is additional amendments are suggest. Also discussed was the restriction based on original presentation. It was agreed that the essence of the restricted claims were already searched. Applicants Representative suggested amending claims 14 and 15 into independent form, and canceling claim 13 to moot the restriction. The examiners agreed to revisit the restriction. The Sha reference was also discussed. The examiners pointed out that Sha does not explicitly state that the liposome is complexed, as opposed to the invention where there is encapsulation. The examiners suggested that a declaration by a third party stating that the procedure used in Sha results in complexation and not encapsulation would be desirable.

Restriction

The Office Action (Paper No. 11) de facto restricts claims 14-17 as being allegedly directed to a non-elected invention based on original presentation. Applicants respectfully traverse this restriction.

By this amendment, claim 16 was cancelled without prejudice or disclaimer, and claims 14-15 and 17 were amended.

Specifically, claims 14-15 were place in independent form and 17 was amended to depend from claim 15, and to recite additional method steps of encapsulating the plasmid. These claims more clearly recite the encapsulation of the plasmid in a liposome formulation. Applicants believe these claims should no longer be subject to a restriction.

Still further, since original claim 6 was directed towards "a liposome-encapsulated DNA vaccine ..." and was not subject to a restriction, then, by original presentation, the additional steps recited in claims 14-15 and 17 of encapsulating the plasmid in a liposome formulation should **not** be subject to restriction.

Accordingly, withdrawal of the restriction of claims 14-17 is respectfully requested.

Additionally, as this Restriction is improper, and no art rejections have been made against claims 14, 15 and 17, these claims are deemed allowable and in condition for allowance. Notice to that effect is hereby requested.

Rejections under 35 U.S.C. §112

Claims 10-11 are rejected under 35 U.S.C. §112, second paragraph for indefiniteness for allegedly failing to set forth any active, positive steps. By this Amendment, claim 10 was amended to recite that for the deoxyribonucleic acid (DNA) vaccine of claim 8, the vaccine prevents or treats an influenza virus infection. Additionally, claim 11 was amended to recite that for the deoxyribonucleic acid (DNA) vaccine of claim 8, the vaccine elicits long-lasting protective antiviral immune responses against influenza viruses. Accordingly, these claims properly limit the independent claim from which they depend. Withdrawal of this rejection is respectfully requested.

Rejections under 35 U.S.C. §101

Claims 10-11 are rejected under 35 U.S.C. §101 for allegedly failing to be a proper process claim. As discussed above, claim 10 was amended to recite that for the deoxyribonucleic acid (DNA) vaccine of claim 8, the vaccine prevents or treats an influenza virus infection. Additionally, claim 11 was amended to recite that for the deoxyribonucleic acid (DNA) vaccine of claim 8, the vaccine elicits long-lasting protective antiviral immune responses against influenza viruses. Accordingly, these claims properly limit the independent claim from which they depend. Withdrawal of this rejection is respectfully requested.

Rejections under 35 U.S.C. §102

Claims 8-11, 17 and 18 are rejected under 35 U.S.C. §102(b) as being unpatentable over Immunobiology, p. 21 - 30 (1999) by Sha et al. ("Sha"). Applicants respectfully traverse this rejection.

Applicants note that the examiner has withdrawn claim 17 from examination, and that there is no apparent rejection of claim 19, although claim 19 is identified as a rejected claim in the Disposition of Claim on form PTO-326. Accordingly, Applicants believe this was a typographical error, and that this rejection should be applied to claims 8-11 and 18-19.

Claim 8 recites a deoxyribonucleic acid (DNA) vaccine comprising a liposome-encapsulated plasmid containing a gene encoding for hemagglutinin protein.

Sha discloses the use of a plasmid/liposome mixture to induce mucosal immunity. Under this approach, the plasmid is mixed with a commercially available liposome made from Dosper (materials and methods, p. 22, lines 8 to 10). The plasmid formed a complex with the liposomes, and the complex is a DNA/liposome mixture.

The Office Action alleges that the claims are not drawn to the specific liposome compositions but to a polynucleotide vaccine, and therefore Applicant's previous arguments were not persuasive. However, the claim is for a liposome-encapsulated plasmid containing a gene encoding for hemagglutinin protein, and both the formulation and the process for making, is disclosed in detail in the specification. That is, Applicants are not required to limit the claims to a specific liposomal formulation, but rather the formulation can be determined from the specification, and cannot be considered as reading a limitation from the specification into the claim. Rather, the formulation is defined in the specification, and as such, need not be recited in

the claim.

The Office Action alleges that the liposome-encapsulated DNA vaccine in the Sha is the same as the liposome-encapsulated plasmid containing a gene encoding for hemagglutinin protein of claim 8. However, the examiner failed to understand that the liposome-encapsulated DNA vaccine **failed** in the Sha study, as well as the reason why the design of the liposome-encapsulated DNA vaccine failed in the Sha study as being almost entirely dependant on specific liposome design and method of encapsulation. In the Sha study, the liposomes were complexed to the DNA vaccine. In contrast, **the plasmid in the present application is encapsulated in liposomes** and are different in design. This is determinative of the failure or success of the resulting vaccine. Furthermore, this invention represents a significant improvement on the vaccine design, and the vaccine efficacy reflects the novelty/distinctiveness of the invention.

A document can only anticipate a claim if the document discloses, explicitly or implicitly, each and every feature recited in the claim. Verdegall Bros. v. Union Oil Co. of Calif., 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Since Sha fails to disclose, either explicitly or implicitly, teach or suggest at least the above-noted elements recited in independent claim 8, Sha cannot anticipate the claims. At least in view of the foregoing, claim 8 is allowable, and the rejection should be reconsidered and withdrawn.

Additionally, claims 9-11 and 18-19, being dependent upon allowable claim 8, are also allowable for the reasons above. Moreover, these claims are further distinguished by the additional features recited therein, particularly within the claim combination.

Accordingly, withdrawal of the §102 rejection is respectfully requested.

Still further, the Office Action alleges that "Sha further comments on the lack of protection in the live virus challenge and associates it with experimental design and not vaccine failure." Office Action at page 4, lines 15-16. It should be noted in Sha acknowledges only that the test failed because of experimental design, and that there is no evidence in Sha that had the correct design been used, the results would have been different. For the examiner to apply the conclusion that the failure was not a result of vaccine failure, the rejection has all the appearance of taking official notice. Applicants respectfully traverse this rejection.

Applicant, by this Amendment, hereby requests that the Examiner either:

1. provides an affidavit attesting to all the elements taken as Official Notice; or

2. provides another non-final Office Action withdrawing Official Notice and, if the Examiner wishes to maintain this rejection, provide suitable references for the asserted rejection.

Since the Examiner's Official Notice is hereby challenged, under M.P.E.P. § 2144.03, 37 C.F.R. 1.104, this is a full and complete response to the pending rejection. Withdrawal of this rejection is respectfully requested.

Still further, Sha states that "Further optimization and modification of the immunization is needed to provide optimal protection against live virus challenge." See page 28, end of second paragraph. Applicants assert that this is no more than an invitation to experiment, and does not rise to the level of anticipation.

Withdrawal of this rejection is respectfully requested.

Rejections under 35 U.S.C. §103

Claims 12 and 13 are rejected under 35 U.S.C. §103(a) as being unpatentable over Immunobiology, p. 21 - 30 (1999) by Sha et al. ("Sha") and Promega Technical Bulletin 206, rev. 7/1999 ("Promega"). By this Amendment claim 13 was canceled without prejudice or disclaimer, mooting this portion of the rejection. Applicants respectfully traverse this rejection.

Claim 12 recites a plasmid vector construct pCI-HA10 comprising a gene encoding for hemagglutinin protein and capable of expressing said hemagglutinin protein in a host, said plasmid vector construct encapsulated in a liposome formulation.

As discussed above, Sha discloses the use of a plasmid/liposome mixture to induce mucosal immunity. Under this approach, the plasmid is mixed with a commercially available liposome made from Dosper (materials and methods, p. 22, lines 8 to 10). The plasmid formed a complex with the liposomes, and the complex is a DNA/liposome mixture. Sha does not disclose, teach or suggest a plasmid vector construct pCI-HA10 comprising a gene encoding for hemagglutinin protein and capable of expressing said hemagglutinin protein in a host, said plasmid vector construct encapsulated in a liposome formulation.

As discussed previously, the Promega reference fails to compensate for the deficiency of Sha. Promega is cited only for its alleged teachings of the use of a pCI plasmid with a CMV

promoter to clone the HA gene.

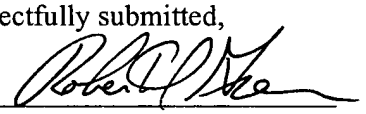
Accordingly, Sha and Promega, taken individually or in view of each other, do not teach or suggest the claimed invention, and cannot render the claims unpatentable. At least in view of the foregoing, claim 12 is allowable, and the rejection should be reconsidered and withdrawn.

Conclusion

For the foregoing reasons, claims 8-12, 14-15 and 17-19 are allowable, and the present application is in condition for allowance. Accordingly, favorable reexamination and reconsideration of the application in light of these amendments and remarks is courteously solicited. If the examiner has any comments or suggestions that would place this application in even better form, the Examiner is requested to telephone the undersigned attorney at the number below.

Dated: October 3, 2003

Respectfully submitted,

By 

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Should additional fees be necessary in connection with the filing of this paper, or if a petition for extension of time is required for timely acceptance of same, the Commissioner is hereby authorized to charge Deposit Account No. 180013 for any such fees; and applicant(s) hereby petition for any needed extension of time.